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Cor

Notice of Allowability	Application No.	Applicant(s)	
	09/724,915	NAKAYAMA ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/07/2004.
2. ☒ The allowed claim(s) is/are 58-74.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

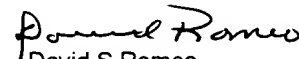
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|--|--|


 David S. Romeo
 Primary Examiner
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DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/07/2004 has been entered.

Claims 58-74 are pending and allowable.

How the examiner construes claim 64

Claim 64 is directed to an isolated nucleic acid molecule encoding a polypeptide wherein the polypeptide comprises amino acids 22-x of SEQ ID NO: 8 or amino acids y-452 of SEQ ID NO: 8, wherein x and y are indeterminate amino acids of SEQ ID NO: 8, such that amino acids 22-x of SEQ ID NO: 8 or amino acids y-452 of SEQ ID NO: 8 retain the capacity to bind BMP-4. In the case where the polypeptide comprises amino acids 22-x of SEQ ID NO: 8, the polypeptide does not comprise anything after amino acid x. Although additions prior to amino acid 22 are permitted. In the case where the polypeptide comprises amino acids y-452 of SEQ ID NO: 8, the polypeptide does not comprise anything prior to amino acid y. Although additions after amino acid 452 are permitted.

Prior art made of record

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EDWARDS (U. S. Patent No. 6783961) discloses an isolated nucleic acid molecule (SEQ ID NO: 632) comprising nucleotides 121-418 of the present application's SEQ ID NO: 7, as indicated below:

```
5  RESULT 4
   US-09-513-999C-632
   ; Sequence 632, Application US/09513999C
   ; Patent No. 6783961
   ; SEQ ID NO 632
10  ; LENGTH: 300
   ; TYPE: DNA
   ; ORGANISM: Homo sapiens
   ; FEATURE:
   ; NAME/KEY: CDS
15  ; LOCATION: 12..299
   ; FEATURE:
   ; NAME/KEY: sig_peptide
   ; LOCATION: 12..74
   ; OTHER INFORMATION: score 5.8
20  ; OTHER INFORMATION: seq SLLFLLLEGGKT/EQ
   US-09-513-999C-632

   Query Match      19.9%; Score 298.4; DB 4; Length 300;
   Best Local Similarity 99.7%; Pred. No. 1.2e-85;
25  Matches 299; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

   QY      121 AAAAGTGGAAAATGGGAGGCATGAAATACATCTTTTCGTTGTTGTCTTTCTTTTGCTAG 180
       |||
   Db      1 AAAAGTGGAAAATGGGAGGCATGAAATACATCTTTTCGTTGTTGTCTTTCTTTTGCTAG 60

30  QY      181 AAGGAGGCAAAACAGAGCAAGTAAACATTTCAGAGACATATTGCATGTTTCAAGACAAGA 240
       |||
   Db      61 AAGGAGGCAAAACAGAGCAAGTAAACATTTCAGAGACATATTGCATGTTTCAAGACAAGA 120

35  QY      241 AGTACAGAGTGGGTGAGAGATGGCATCCTTACCTGGAACCTTATGGGTTGGTTTACTGCG 300
       |||
   Db      121 AGTACAGAGTGGGTGAGAGATGGCATCCTTACCTGGAACCTTATGGGTTGGTTTACTGCG 180

   QY      301 TGAAGTGCATCTGCTCAGAGAAATGGGAATGTGCTTTGCAGCCGAGTCAGATGTCCAAATG 360
       |||
40  Db      181 TGAAGTGCATCTGCTCAGAGAAATGGGAATGTGCTTTGCAGCCGAGTCAGATGTCCAAATG 240

   QY      361 TTCATTGCCTTTCTCCTGTGCATATTCTCATCTGTGCTGCCCTCGCTGCCCAAGAGT 420
       |||
45  Db      241 TTCATTGCCTTTCTCCTGTGCATATTCTCATCTGTGCTGCCCTCGCTGCCCAAGAGT 300.
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EDWARDS's SEQ ID NO: 632 encodes a polypeptide (SEQ ID NO: 4709) that comprises amino acids 1-95 of the present application's SEQ ID NO: 8, as indicated below:

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50  RESULT 2
   US-09-513-999C-4709
   ; Sequence 4709, Application US/09513999C
   ; Patent No. 6783961
   ; SEQ ID NO 4709
55  ; LENGTH: 96
   ; TYPE: PRT
   ; ORGANISM: Homo sapiens
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; FEATURE:
; NAME/KEY: SIGNAL
; LOCATION: -21...-1
; OTHER INFORMATION: score 5.8
5 ; OTHER INFORMATION: seq SLLFFLLLEGGKT/EQ
US-09-513-999C-4709

Query Match          21.8%; Score 554; DB 4; Length 96;
Best Local Similarity 99.0%; Pred. No. 5.3e-46;
10 Matches 95; Conservative 1; Mismatches 0; Indels 0; Gaps 0;

Qy      1 MGGMKYIFSLFFLLLEGGKTEQVKHSETYCMFQDKKYRVGERWHPYLEPYGLVYCVNCI 60
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
15 Db      1 MGGMKYIFSLFFLLLEGGKTEQVKHSETYCMFQDKKYRVGERWHPYLEPYGLVYCVNCI 60

Qy      61 CSENGNVLC SRVRCPNVHCLSPVHIPHLCCPRCPED 96
        ||||||||||||||||||||||||||||||||||||:
Db      61 CSENGNVLC SRVRCPNVHCLSPVHIPHLCCPRCP EE 96.

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20 The CR1 and CR3 motifs of the present application's CHL polypeptide (SEQ ID NO: 8) were particularly found to be highly homologous to the CR3 of CHD/SOD. See the present specification at page 96, lines 8-10.

The CR1 motif of the present application's CHL polypeptide (SEQ ID NO: 8) consists of amino acids 32-94 of SEQ ID NO: 8, as evidenced by Nakayama (page 374, Figure 1) (Cite No. 25 16, cited by Applicants). Therefore, EDWARDS's SEQ ID NO: 632 encodes a polypeptide (SEQ ID NO: 4709) that comprises the CR1 motif of the present application's CHL polypeptide (SEQ ID NO: 8).

Nakayama (Cite No. 16, cited by Applicants) also discloses that the CRs are the binding sites for BMPs (page 384, paragraph bridging left and right columns). Larrain (U) discloses that 30 the biological activity of Chordin resides in the CRs, especially in CR1 and CR3, which bind BMP4 (page 821, Summary). Therefore, EDWARDS discloses an isolated nucleic acid molecule that encodes a polypeptide comprising amino acids 22-95 of SEQ ID NO: 8, wherein the polypeptide retains the capacity to bind BMP-4. However, EDWARDS does not disclose an isolated nucleic acid molecule encoding a polypeptide, wherein the polypeptide comprises amino

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acids 22-95 of SEQ ID NO: 8, and wherein the polypeptide does not comprise anything after amino acid 95.

The 35 U.S.C. § 102(e) prior art date of EDWARDS is the filing date of provisional application 60/122,487 (V).

5

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

10 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

15 FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
MARCH 3, 2005